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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,946	09/22/2003	Baldomero M. Olivera	2314-266	7093

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EXAMINER	
CARLSON, KAREN C	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,946	OLIVERA, BALDOMERO M.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *19-31 and 35-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/5/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group II, Claims 1-18 and 32-34, drawn to a method for protecting an organ in a subject by administering kM conopeptide and adenocine receptor agonists in the reply filed on July 20, 2006 is acknowledged. The traversal is on the ground(s) that arresting, protecting, and preserving are defined at page 3 and that the definitions are overlapping. Further, that the definitions refer to the same method. Upon further perusal of the specification, at page 4, para. [0016], the term "protect" is intended to included "arrest" and "preserve". Therefore, the Examiner has rejoined Groups I-III.

The remainder of the requirement is still deemed proper and is therefore made FINAL.

Claims 1-18 and 32-34 are under examination. Claims 19-31 and 35-38 are drawn to non-elected inventions and have been withdrawn from further consideration by the Examiner.

Priority is to September 20, 20002.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, it is not clear what an organ is being protected/arrested/preserved from. It is not clear how one would identify a subject in need thereof, that is, who is in need of kM conopeptide?

In Claim 3, the organ can be in the body of the subject or isolated from the subject. It is not clear how administering kM conopeptide to a subject will affect an isolated organ outside of the subject. Further, the organ being isolated from the subject lacks antecedent basis in Claim 2.

Claim 5 is unclear because, for example, it is not clear if a circulatory organ comprises only the heart, or includes blood vessels or other organs. It is not clear if a urinary organ is the kidneys, or includes the bladder, for example. See the entire list or organs in Claim 5. Also, Claim 5 refers to organs selected from the group consisting of, and this list includes a somatic cell. A somatic cell is not an organ and therefore this claim is indefinite.

The circulatory organ of Claim 6 lacks antecedent basis in Claim 1. It appears that Claim 6 should depend from Claim 5.

Claims 8, 9, 11, 12, 14, and 15 mirror Claims 5 and 6 and are indefinite for the same reasons that Claims 5 and 6 are indefinite.

Claim 32-34 depend from Claim 1 and refer to "each agent or combination of agents". Claim 1 refers to a single agent; thus, Claim 32 lacks antecedent basis in Claim 1.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivera et al. (WO 02/07678, published January 31, 2002).

Olivera et al. teach SEQ ID NO: 190, having the amino acid sequence:

Leu Pro Ser Cys Cys Ser Leu Asn Leu Arg Leu Cys Pro Val Pro Ala Cys Lys Arg Asn Pro Cys Cys Thr

At page 4, paras. [0019] and [0020], the instant specifications states that the κM-RIIIK peptide is a peptide having this same sequence, that is, instant SEQ ID NO: 1.

Olivera et al. discuss μ-conopeptides comprising SEQ ID NO: 190. At page 4, line 2; page 6, line 19, Olivera et al. state that these peptides can be used as neuroprotective agents. At the sentence bridging pages 6 and 7, at page 9, para. [0033], and at page 16, para. [0058], Olivera et al. state that these peptides are also useful for condition of hypoxia, anoxia, or ischemia which typically follows stroke, cerebrovascular accident, brain or spinal cord trauma, and myocardial infarct, physical trauma, suffocation, perinatal asphyxia, or hypoglycemic events.

Olivera et al. state that these peptides can be administered orally (page 18, [0067], rectally, epidurally, intravenously, intramuscularly, subcutaneously, intranasally, transdermally, sublingually, by irrigation, by release pump, or by infusion. Olivera et al. also state that the peptide can be delivered into the brain ventricles (intracerbralventricularly) or into the intrathecal space (page 19, [0071]). Olivera et al. also state that the peptides can be administered by continuous release polymer pumps (page 19, [0700] at (c) and page 21, line 1) or in multiple does per day (page 21, line 2).

Therefore, it would have been obvious to a person having ordinary skill in the art to protect an organ of a mammalian subject by administering an effective amount of κM peptide (Claim 1, 3), wherein the peptide is κM-RIIIK peptide as defined in SEQ ID NO: 1 (Claim 2, 4) because Olivera et al. state that this peptide is useful as a neuroprotective agent.

It would have been obvious to a person having ordinary skill in the art to protect organs such as the heart (Claim 5, 6, 8, 9, 11, 12, 14, 15), respiratory organs, urinary organs, digestive organs, reproductive organs, endocrine organs, and neurological organs, and somatic cells (Claim 5, 8, 11, 14), and protect the heart during cardiovascular intervention to protect against ischemia (Claim 7, 10, 13, 16) by administering κM-RIIIK peptide because Olivera et al. state that these peptides are also useful for condition of hypoxia, anoxia, or ischemia which typically

follows stroke, cerebrovascular accident, brain or spinal cord trauma, and myocardial infarct, physical trauma, suffocation, perinatal asphyxia, or hypoglycemic events.

It would have been obvious to a person having ordinary skill in the art to administer the κM-RIIIK peptide orally, rectally, epidurally, intravenously, intramuscularly, subcutaneously, intranasally, transdermally, sublingually, by irrigation, by release pump, by infusion. intracerbralventricularly, or into the intrathecal space (Claim 32) because Olivera et al. state that these modes of administration are useful for delivery of the κM-RIIIK peptide to its site of action. Further, it would have been obvious to administer κM-RIIIK peptide continuously or intermittently because Olivera et al. state that the peptides can be administered by continuous release polymer pumps or in multiple does per day (Claim 33).

Claims 1-16, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivera et al. (USP 6,727,226; priority to at least July 23, 2001).

Olivera et al. teach SEQ ID NO: 190, having the amino acid sequence:
Leu Pro Ser Cys Cys Ser Leu Asn Leu Arg Leu Cys Pro Val Pro Ala Cys Lys Arg Asn Pro Cys Cys Thr

At page 4, [0019] and [0020], the instant specifications states that the κM-RIIIK peptide is a peptide having this same sequence, that is, instant SEQ ID NO: 1.

Olivera et al. discuss μ-conopeptides comprising SEQ ID NO: 190. At col. 3, line 13; col. 5, line 9, Olivera et al. state that these peptides can be used as neuroprotective agents. At col. 5, lines 27-33, at col. 11line 64 to col. 12, line 8, Olivera et al. state that these peptides are also useful for condition of hypoxia, anoxia, or ischemia which typically follows stroke, cerebrovascular accident, brain or spinal cord trauma, and myocardial infarct, physical trauma, suffocation, perinatal asphyxia, or hypoglycemic events.

Olivera et al. state that these peptides can be administered orally (col. 13, line 42+), rectally, epidurally, intravenously, intramuscularly, subcutaneously, intranasally, transdermally, sublingually, by irrigation, by release pump, or by infusion. Olivera et al. also state that the peptide can be delivered into the brain ventricles (intracerbralventricularly) or into the intrathecal space (col. 14, lines 39-40). Olivera et al. also state that the peptides can be administered by continuous release polymer pumps (col. 14, line 27 at (c) and col. 15, line 1) or in multiple does per day (col. 15, line 1).

Therefore, it would have been obvious to a person having ordinary skill in the art to protect an organ of a mammalian subject by administering an effective amount of κM peptide (Claim 1, 3), wherein the peptide is κM-RIIIK peptide as defined in SEQ ID NO: 1 (Claim 2, 4) because Olivera et al. state that this peptide is useful as a neuroprotective agent.

It would have been obvious to a person having ordinary skill in the art to protect organs such as the heart (Claim 5, 6, 8, 9, 11, 12, 14, 15), respiratory organs, urinary organs, digestive organs, reproductive organs, endocrine organs, and neurological organs, and somatic cells (Claim 5, 8, 11, 14), and protect the heart during cardiovascular intervention to protect against ischemia (Claim 7, 10, 13, 16) by administering κM-RIIIK peptide because Olivera et al. state that these peptides are also useful for condition of hypoxia, anoxia, or ischemia which typically follows stroke, cerebrovascular accident, brain or spinal cord trauma, and myocardial infarct, physical trauma, suffocation, perinatal asphyxia, or hypoglycemic events.

It would have been obvious to a person having ordinary skill in the art to administer the κM-RIIIK peptide orally, rectally, epidurally, intravenously, intramuscularly, subcutaneously, intranasally, transdermally, sublingually, by irrigation, by release pump, by infusion. intracerbralventricularly, or into the intrathecal space (Claim 32) because Olivera et al. state that these modes of administration are useful for delivery of the κM-RIIIK peptide to its site of action. Further, it would have been obvious to administer κM-RIIIK peptide continuously or

intermittently because Olivera et al. state that the peptides can be administered by continuous release polymer pumps or in multiple does per day (Claim 33).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER